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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,484	05/07/2001	Bernhard Fischer	37974-0156	1519

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EXAMINER
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ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

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DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/849,484	FISCHER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Hope A. Robinson	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 November 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 19 and 44-63 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 19 and 44-63 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The preliminary amendment filed on May 7, 2001 has been received and entered.

***Specification***

2. The disclosure is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed and they are not capitalized. The use of the trademark Heparin EMD-Fraktogel®, Heparin-Sepharose Fast Flow® and AF-Heparin Toyopearl ® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology, see for example page 20, lines 10-15. .

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction is required.

***Claim Disposition***

3. Claims 1-18 and 20-43 have been canceled. Claims 44-63 have been added. Claims 19 and 44-63 are pending and under examination.

***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in on March 15, 1996. It is noted, however, that applicant has not filed a certified copy of the application (Austria A 494/96) as required by 35 U.S.C. 119(b).

**Information Disclosure Statement**

5. The information disclosure statement filed on October 25, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement were not translated or are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following item on the information disclosure statement: EP0705846 (German language document, no English abstract or English equivalent found), EP416,983 (French language, no English abstract or English equivalent found) and DE3504385A1 (Denmark document) which is missing from the instant application and the parent application. In addition, WO96/10584, German language, has only been considered to the extent that it has an English abstract.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 19 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Note that claim 19 is directed to a method of recovering stable factor VIII/vWF-complex however, the method has no positive method steps. The method reports that the complex is bound to heparin affinity carrier and is recovered at a low salt concentration, however, there are no steps to recovery the protein. Note also that claims 8, 18 and 22 recite methods that provide results rather than method steps, which does not set forth what method/process is encompassed. Without setting forth any steps involved in the process/method, results in an improper definition of a process and is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-56 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 44 and the dependent claims hereto are indefinite because the claim lacks antecedent basis for the recitation of "eluting the contaminating proteins with an eluting agent containing a salt concentration of  $\leq$  200 m M and CaCl<sub>2</sub> and subsequently recovering Factor VIII/vWF from the anion exchanger at a salt concentration of between  $\geq$  200 m M and  $\leq$  400 m M", because the disclosure on page 19 states that "calcium salts are not suitable for elution". The elution step to remove contaminating proteins has a protein solution containing Factor VIII/vWF-complex and contaminating proteins. Further, it is known in the art that calcium salts disrupts the Factor VIII/vWF-complex. The claim is also indefinite for the recitation of "vWF" as this acronym could mean "Vincent William Flack", therefore, at the independent claims need to recite the spelled out meaning "von Willebrand Factor", see also claim 57 for the same and claim 63 for "vWF:Ag" which should be spelled out as "von Willebrand Factor antigen".

Claim 56 is indefinite because the claim contains the trademark/trade name Heparin EMD-Fraktogel®, Heparin-Sepharose Fast Flow® and AF-Heparin Toyopearl ®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe the preparation and, accordingly, the identification/description is indefinite.

Claims 57, 59 and 60 are indefinite because the preamble of the claim recites " a method of recovering a stable Factor VIII/vWF-complex" and the first step in the method is to "subject Factor VIII or a Factor VIII/vWF-complex to a chromatographic treatment to provide purified Factor VIII or Factor **VIIII/vWF**" and the Factor VIII is a different product than the Factor VIII/vWF-complex which is not recited in the preamble. Note also the "Factor VIII" is represented as "Factor **VIIII**" in line 4 of claim 57 which renders the claim indefinite as the Roman number for nine is X not VIIII and the claims are directed to Factor VIII not Factor X.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Arrighi et al. (EP 600480, June 8, 1994.

Arrighi et al. teach a process for extraction of Factor VIII-von Willebrand Factor complex (claim 57) from total human plasma (claim 59, column 1, lines 1-3) comprising subjecting the Factor VIII/vWF complex to chromatographic treatment (claim 57, see anionic exchange chromatography column 1, lines 9-10). Arrighi et al. teach that the solution consists of a FVIII:C-FvW complex eluted in 1:1 ratio which falls within the ratio range of "0.01 and 100" recited in the claim. The claim recites admixing a purified high molecular weight fraction of vWF molecules to the purified Factor VIII or Factor VIII/vWF complex to obtain the above ratio. It is well known in the prior art that high molecular weight vWF is an intrinsic property of vWF, therefore, is included in the ratio (column 3, lines 20-25, claim 56). Note also that the range disclosed by the reference falls with the range recited in claim 58 "0.05 and 1" (claim 58). Arrighi et al. teach that the Factor VIII/vWF is obtained from supernatant and supernatant which is expected to be free of cells and the reference teach that the supernatant is subjected to filtration, thus, claim 60 is anticipated (column 2, line 53 and column 6, lines 21-22). Thus, the limitations of the claims are met by this reference.

### ***Conclusion***

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS<sup>10</sup>

Patent Examiner

*Christopher S. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600